



Epic Medical Equipment Services

1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

0551

July 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

RE: Comments – proposed rule [Docket No. 98N-0583]

The FDA Export Reform and Enhancement Act was passed in 1996 with the intent to streamline and simplify the process for exporting medical devices not yet approved by FDA.

Our firm is concerned that the proposed rule is unnecessary and defeats the intent of the statute by imposing an unnecessary and cumbersome recordkeeping burden on the industry, rather than simplifying the process. As an exporter of medical devices, we are aware of the dependence of other countries on medical technology from the US, and we are concerned that this proposed rule would be detrimental to these countries.

Our firm believes that the statute does not require administrative interpretation to the extent provided in the proposed rule.

As such, our firm believes that this proposed rule should be withdrawn.

Sincerely,

Krista Oakes

Vice President, Regulatory Affairs & Quality Assurance

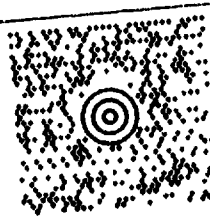
98N-0583

C14

W
Olym

EPIC MEDICAL EQUIPMENT SERVICE
(972) 801-9854
1800 10TH ST. STE300
PLANO TX 75074-8002

SHIP DOCKETS & MANAGEMENT BRANCH
TO: FOOD & DRUG ADMINISTRATION
RM 1061
5630 FISHERS LANE
ROCKVILLE MD 20852



MD 2070-10



UPS NEXT DAY AIR 1

TRACKING #: 12 E79 359 01 4064 9067



PKG REF 1:KRISTA O.

your address label
the left of the address label
number or place parcel register tape above the address label
ent

PRO 6 0 1814 E2543



Warning: Please Read Shipping Notice. Carriage hereunder may be subject to the rules relating to liability and other terms, under conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (the "Warsaw Convention") and/or the Convention on the Contract for the International Carriage of Goods by Road (the "CMR Convention"). These commodities, technology or software were exported from the U.S. in accordance with the Export Administration Regulations. Destruction contrary to U.S. law prohibited. United Parcel Service, Louisville, KY. For shipping plans, call 1-800-762-7832.